ISRCTN53816305 https://doi.org/10.1186/ISRCTN53816305

Therapy efficacy, compliance and long-term outcome of Auto-bilevel therapy compared to continuous positive airway pressure (CPAP) therapy in obstructive sleep apnoea (OSA) patients

Submission date
29/10/2008

Recruitment status
No longer recruiting

Registration date
11/12/2008

Overall study status
Completed

Last Edited
20/11/2012

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Ingo Fietze

Contact details
Center of Sleep Medicine
Department of Internal Medicine
Charité-Universitätsmedizin Berlin, CCM
Luisenstr. 13
Berlin
Germany
10117
ingo.fietze@charite.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
EAME05AUTOBILEVEL01

Study information

Scientific Title

Acronym
AUTOBILEVEL

Study objectives
We hypothesised that auto-bilevel therapy would be equivalant to fixed continuous positive airway pressure (CPAP) therapy on parameters of objective and subjective compliance and therapeutic effectiveness in patients with moderate to severe obstructive sleep apnoea.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethikkommission of Charite Campus-Mitte gave approval on the 1st March 2006 (ref: EA1/044 /08)

Study design
Controlled, double-blind randomised study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Obstructive sleep apnoea

Interventions

After a CPAP titration night patients will be randomised to three months of either BiPAP auto with Biflex or fixed level CPAP. Patients will be followed up at 1, 4, 8 and 12 weeks.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Treatment and therapeutic efficacy will be measured by polysomnography (PSG) at diagnosis, titration and 12 weeks (end of study).

Secondary outcome measures
1. Objective compliance measured by device memory download at one week and the end of the study
2. Subjective compliance and parameters of wellbeing measured at baseline, 4, 8, 12 weeks
3. Epworth Sleepiness Scale measured at baseline (after diagnostic PSG and after titration PSG), 4, 8 and 12 weeks
4. Pittsburgh Sleep Quality Index measured at baseline (after diagnostic PSG only), 4, 8 and 12 weeks
5. Functional Outcomes of Sleep Questionnaire measured at baseline (after diagnostic PSG only), 4, 8 and 12 weeks
6. Calgary Sleep Apnoea Quality of Life Index measured at baseline (after diagnostic PSG only), 4, 8 and 12 weeks
7. 12-item Short Form (SF-12) measured at baseline (after diagnostic PSG only), 4, 8 and 12 weeks
8. Visual Analogue Scale measured in the morning and evening at baseline (after diagnostic PSG and after titration PSG), 4, 8 and 12 weeks
9. Treatment Satisfaction Visual Analogue Scale measured at baseline (after titration PSG only), 4, 8 and 12 weeks
10. Treatment Comfort Visual Analogue Scale measured at baseline (after titration PSG only), 4, 8 and 12 weeks
11. Mask/Interface Comfort Visual Analogue Scale measured at baseline (after titration PSG only), 4, 8 and 12 weeks

Overall study start date
05/06/2006

Completion date
09/06/2007

Eligibility

Key inclusion criteria
1. Apnoea/Hypopnoea Index (AHI) greater than 15/h
2. Aged greater than or equal to 21 years and less than or equal to 65 years, either sex
3. Body mass index (BMI) less than 40 kg/m^2
4. Able to follow the study protocol
5. Successful CPAP titration

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
32

Key exclusion criteria
1. Drug abuse
2. Intake of central relevant drugs, sedatives, or other drugs with impairment of sleep
3. Alcohol abuse; consume more than 30 g/d
4. Participation in other clinical-pharmacological studies up to 4 weeks prior of study begin
5. Psychiatric or neurological diseases resulting in impairment of sleep, therapy or compliance
6. Thyroidal dysfunction
7. Chronic pain syndromes
8. Acute cardiac, pulmonary, and other internal diseases
9. Chronic cardiac, pulmonary and other internal diseases resulting in impairment of sleep
10. Central sleep-related breathing disorders or other disorders resulting in hypoventilation
11. Periodic leg movements (PLM)/restless legs syndrome (RLS)
12. Previous exposure to either CPAP or bilevel therapy

Date of first enrolment
05/06/2006

Date of final enrolment
09/06/2007

Locations

Countries of recruitment
Germany

Study participating centre
Center of Sleep Medicine
Berlin
Germany
10117

Sponsor information

Organisation
Respironics International, Inc. (France)

Sponsor details
20 Rue-Jacques Daguerre
Rueil-Malmaison
Paris
France
92500
steven.coughlin@respironics.com

Sponsor type
Industry

Website
http://www.respironics.com/

ROR
https://ror.org/05jz46060

Funder(s)

Funder type
Industry

Funder Name
Respironics International, Inc. (France)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2012		Yes	No